

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED REVIEW (CON) STANDARDS FOR NEONATAL INTENSIVE CARE SERVICES/BEDS

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207 and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve neonatal intensive care services/beds.

(2) The initiation, expansion, relocation, or replacement of neonatal intensive care services/beds is a covered clinical service for purposes of Part 222 of the Code.

~~—(3) A change in designation between NICU and SNNU without changing the number of licensed hospital beds designated for NICU/SNNU is not a covered clinical service for purposes of Part 222 of the Code.~~

(43) The Department shall use sections 3, 4, 5, 6, 7, ~~8~~, and ~~98~~, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

~~(54)~~ The Department shall use Section 11, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

(5) THE DEPARTMENT SHALL USE SECTION 10, AS APPLICABLE, IN APPLYING SECTION 22215(1)(B) OF THE CODE, BEING SECTION 333.22215(1)(B) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Acquisition of a NICU" means the issuance of a new license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of existing licensed hospital beds designated for NICU services at the same site which does not involve a change in bed capacity or a relocation of the designation of beds for NICU services.

(b) "Bassinet" means an unlicensed bassinet in the obstetrical or newborn service that provides care for the uncomplicated newborn.

(c) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(d) "Code" means Act No. 368 of the Public Acts of 1978 as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(e) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON rules.

(f) "Department" means the Michigan Department of Community Health (MDCH).

(g) "Department inventory of beds" means the current list, for each planning area maintained on a continuous basis by the Department of: ~~—(i) licensed hospital beds designated for NICU services; and (ii)~~ NICU beds with valid CON approval but not yet licensed or designated.

(h) "Existing NICU beds" means the total number of all of the following:

- (i) licensed hospital beds designated for NICU services;
- (ii) NICU beds with valid CON approval but not yet licensed or designated;
- (iii) NICU beds under appeal from a final decision of the Department; and

~~_____~~ (iv) proposed NICU beds that are part of ~~AN completed~~ application ~~under Part 222 (other than the application under review)~~ for which a proposed decision has been issued, ~~BUT~~ and which is pending final Department decision. ~~The term includes those beds designated by the department as special newborn nursery unit (SNNU) beds. The term does not include NICU beds approved pursuant to Section 6(2) of these standards.~~

(i) "Expansion of NICU services/~~beds~~" means increasing the number of ~~licensed~~ hospital beds designated for NICU services at a licensed site ~~which as of the effective date of these standards has a licensed and designated NICU or has a valid CON to operate a NICU service, either by an increase in the total number of licensed hospital beds, or the conversion of existing licensed hospital beds from one use to another (i.e. converting medical/surgical beds to pediatric beds designated for NICU).~~

(j) "Hospital" means a health facility licensed under Part 215 of the Code.

(k) "Initiation of NICU services/~~beds~~" means the establishment of a NICU at a licensed site ~~that as of the effective date of these standards~~ has not had in the previous 12 months a licensed and designated NICU or does not have a valid CON to initiate a NICU. The relocation of the designation of beds for NICU services meeting the applicable requirements of Section ~~7-6~~ shall not be considered as the initiation of NICU services/~~beds~~.

(l) "Infant" means an individual up to 1 year of age.

(m) "Licensed site" means either: ~~(i) in~~ the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure; or ~~(ii) in~~ the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(n) "Live birth" means a birth for which a birth certificate for a live birth has been prepared and filed pursuant to Section 333.2821(2) of the Michigan Compiled Laws.

(o) "Maternal referral service" means having a consultative and patient referral service staffed by a physician(s), on the active medical staff, that is board certified, or eligible to be board certified, in maternal/fetal medicine.

(p) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-8 to 1396v.

(q) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(r) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(s) "Neonatal intensive care services" or "NICU services" means the provision of any of the following services:

(i) constant nursing care and continuous cardiopulmonary and other support services for severely ill infants;

(ii) care for neonates weighing less than 1,500 grams at birth;

(iii) ventilatory support beyond that needed for immediate ventilatory stabilization;

(iv) surgery and post-operative care during the neonatal period;

(v) pharmacologic stabilization of heart rate and blood pressure; or

(vi) parenteral nutrition.

(t) "Neonatal intensive care unit" or "NICU" means a specially designed, equipped, and staffed unit of a hospital which ~~meets IS both of the following: (i) is~~ capable of providing neonatal intensive care services; and ~~(ii) is composed of licensed hospital beds designated as NICU on the effective date of these standards or designated under a valid CON held by an applicant to develop this service.~~ This term does not include bassinets or special newborn care bassinets.

(u) "Neonatal transport system" means a specialized transfer program for neonates by means of an ambulance licensed pursuant to Part 209 of the Code, being Section 333.20901 et seq.

(v) "Neonate" means an individual up to 28 days of age.

~~(w) "Offer NICU services" means to provide NICU services to patients.~~

~~(xW)~~ "Perinatal care network," ~~for purposes of these standards,~~ means the providers and facilities within a planning area that provide basic, specialty, and sub-specialty obstetric, pediatric and neonatal

intensive care services.

(yX) "Planning area" means the groups of counties shown in Section 12.

(z) "Planning year" means the most recent continuous 12 month period ~~prior to the applicant's request~~ for which birth data is available from the ~~Office of the State Registrar~~ VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION.

(aa) "Qualifying project" means each application in a comparative group which has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.

(bb) "Relocation of the designation of beds for NICU services" ~~for purposes of these standards,~~ means a change, within the same planning area, in the licensed site at which existing licensed hospital beds are designated for NICU services.

(cc) "Replacement of NICU services/beds" means developing new space, whether through new construction or purchase/lease, to house existing licensed and designated NICU beds.

(dd) "Replacement zone" means a proposed licensed site which is: ~~(i)~~ in the same planning area as the existing licensed site; and ~~(ii)~~ in the area set forth in Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, in which replacement beds in a hospital are not subject to comparative review.

(ee) "Special newborn care bassinet" means an unlicensed bassinet identified within the hospital obstetrical or newborn service which provides the services identified in subsections (i) through (vi) for infants who require minimal care that goes beyond that of the uncomplicated newborn, or transitional care or developmental maturation in preparation for discharge home. Infants receiving transitional care or being treated for developmental maturation may have formerly been treated in a neonatal intensive care unit in the same hospital or another hospital.

(i) Care for low birth weight infants between 1,500 and 2,499 grams;

(ii) enteral tube feedings;

(iii) cardio-respiratory monitoring to document maturity of respiratory control or treatment of apnea;

(iv) antibiotic therapy in an infant not needing ventilatory support or pressor support;

(v) extended care following an admission to a neonatal intensive care unit for an infant not requiring ventilatory support; or

(vi) the administration of oxygen by hood or nasal canula.

(ff) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Bed need methodology

Sec. 3. (1) The number of NICU beds needed in a planning area shall be determined by the following formula:

(a) Determine, using data obtained from the ~~Office of the State Registrar~~ VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, the total number of live births which occurred in the planning year at all hospitals geographically located within the planning area.

(b) Determine, using data obtained from the ~~Office of the State Registrar~~ VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, the percent of live births in each planning area and the state that were less than 1,500 grams. The result is the very low birth weight rate for each planning area and the state, respectively.

(c) Divide the very low birth weight rate for each planning area by the statewide very low birth weight rate. The result is the very low birth weight rate adjustment factor for each planning area.

(d) Multiply the very low birth weight rate adjustment factor for each planning area by 0.0045. The result is the bed need formula for each planning area adjusted for the very low birth weight rate.

(e) Multiply the total number of live births determined in subsection (1)(a) by the bed need formula for the applicable planning area adjusted for the very low birth weight adjustment factor as determined in Potential Proposed Language for March 13, 2007 Commission Meeting

subsection (1)(d).

(2) The result of subsection (1) is the number of NICU beds needed in the planning area for the planning year.

Section 4. Requirement for all applicants

~~— Sec. 4. (1) An applicant proposing to increase the number of licensed hospital beds at the licensed site at which a project involving NICU services/beds is proposed shall demonstrate that an application meets all of the applicable requirements set forth in the CON review standards for Hospital Beds.~~

~~— (2) An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.~~

Section 54. Requirements for applicants proposing TO INITIATE ~~the initiation of~~ NICU services/beds

Sec. 54. ~~(1)~~ An applicant proposing to initiate ~~neonatal intensive care~~ NICU services/beds BY DESIGNATING HOSPITAL BEDS AS NICU BEDS shall demonstrate each of the following:

(a1) There is an unmet bed need of at least 15 NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year as a result of application of the methodology set forth in Section 3.

(b2) Approval of the proposed NICU will not result in a surplus of NICU beds in the planning area based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(c3) A unit of at least 15 beds will be developed and operated.

(d4) For each of the 3 most recent years for which birth data are available from the ~~Office of the State Registrar~~ VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, the licensed site at which the NICU is proposed had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles (surface travel) from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds.

Section 65. Requirements for ~~all~~ applicants proposing to expand NICU services/beds

Sec. 65. (1) An applicant proposing to expand NICU services/beds BY DESIGNATING ADDITIONAL HOSPITAL BEDS AS NICU BEDS in a planning area shall demonstrate that the proposed increase will not result in a surplus of NICU beds based on the difference between the number of existing NICU beds in the planning area and the number of beds needed for the planning year resulting from application of the methodology set forth in Section 3.

(2) An applicant may apply and be approved for NICU beds in excess of the number determined as needed for the planning year in accordance with Section 3 if an applicant can demonstrate that it provides NICU services to patients transferred from another licensed and designated NICU. The maximum number of NICU beds that may be approved pursuant to this subsection shall be determined in accordance with the following:

(a) An applicant shall document the average annual number of patient days provided to neonates or infants transferred from another licensed and designated NICU, for the 2 most recent years for which verifiable data are available to the Department.

(b) The average annual number of patient days determined in accordance with subsection (a) shall be divided by 365 (or 366 for a leap year). The result is the average daily census (ADC) for NICU services provided to patients transferred from another licensed and designated NICU.

(c) Apply the ADC determined in accordance with subsection (b) in the following formula: $ADC + 2.06 ADC$. The result is the maximum number of beds that may be approved pursuant to this subsection

up to 5 beds at each licensed site.

~~—(3) An applicant proposing to expand NICU services/beds in a planning area shall demonstrate that it is in compliance with all applicable requirements of Section 11 on the date an application is submitted to the Department.~~

Section 76. Requirements for approval TO RELOCATE DESIGNATED NICU BEDS. ~~--relocation of the designation of beds for NICU services~~

Sec. 76. An applicant proposing ~~the relocation of the designation of~~ TO RELOCATE DESIGNED beds for NICU services shall demonstrate compliance with all of the following:

(1) The applicant is the licensed site to which the relocation of the designation of beds for NICU services is proposed.

(2) The applicant is a party to a signed written agreement that provides for the proposed increase, and concomitant decrease, in the number of beds designated for NICU services at the 2 licensed sites involved in the proposed relocation. A copy of the agreement shall be provided in the application.

(3) The existing licensed site from which the designation of beds for NICU services proposed to be relocated is currently licensed and designated for NICU services.

(4) The proposed project does not result in an increase in the number of beds designated for NICU services in the planning area unless the applicable requirements of Section 5 or 6 have also been met.

(5) The proposed project does not result in an increase in the number of licensed hospital beds at the applicant licensed site unless the applicable requirements of the CON Rreview Sstandards for Hospital Beds have also been met.

(6) The proposed project does not result in the operation of a NICU of less than 15 beds at the existing licensed site from which the designation of beds for NICU services are proposed to be relocated.

(7) If the applicant licensed site does not currently provide NICU services, an applicant shall demonstrate both of the following:

(a) the proposed project involves the establishment of a NICU of at least 15 beds; and

(b) for each of the 3 most recent years for which birth data are available from the ~~Office of the State Registrar~~ VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, the applicant licensed site had either: (i) 2,000 or more live births, if the licensed site is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the licensed site is located in a rural or micropolitan statistical area county and is located more than 100 miles ~~(surface miles)~~ from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds. If the applicant licensed site has not been in operation for at least 3 years and the obstetrical unit at the applicant licensed site was established as the result of the consolidation and closure of 2 or more obstetrical units, the combined number of live births from the obstetrical units that were closed and relocated to the applicant licensed site may be used to evaluate compliance with this requirement for those years when the applicant licensed site was not in operation.

(8) If the applicant licensed site does not currently provide NICU services or obstetrical services, an applicant shall demonstrate both of the following:

(a) the proposed project involves the establishment of a NICU of at least 15 beds; and

(b) the applicant has a valid CON to establish an obstetrical unit at the licensed site at which the NICU is proposed. The obstetrical unit to be established shall be the result of the relocation of an existing obstetrical unit that for each of the 3 most recent years for which birth data are available from the ~~Office of the State Registrar~~ VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, the obstetrical unit to be relocated had either: (i) 2,000 or more live births, if the obstetrical unit to be relocated is located in a metropolitan statistical area county; or (ii) 600 or more live births, if the obstetrical unit to be relocated

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is located in a rural or micropolitan statistical area county and is located more than 100 miles ~~(surface miles)~~ from the nearest licensed site that operates or has valid CON approval to operate NICU services/beds.

(9) The project results in a decrease in the number of licensed hospital beds that are designated for NICU services at the licensed site at which beds are currently designated for NICU services. The decrease in the number of beds designated for NICU services shall be equal to or greater than the number of beds designated for NICU services proposed to be increased at the applicant's licensed site pursuant to the agreement required by this subsection. This subsection requires a decrease in the number of licensed hospital beds that are designated for NICU services, but does not require a decrease in the number of licensed hospital beds.

(10) Beds approved pursuant to Section 6(2) shall not be relocated pursuant to this section, unless the proposed project involves the relocation of all beds designated for NICU services at the applicant's licensed site.

Section 87. Requirements for approval ~~FOR~~ -- replacement NICU beds

Sec. 87. (1) An applicant proposing replacement beds shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 if an applicant demonstrates all of the following:

(a) the project proposes to replace an equal or lesser number of beds designated by an applicant for NICU services at the licensed site operated by the same applicant at which the proposed replacement beds are currently located;

(b) the proposed licensed site is in the replacement zone; and,

~~—(c) an applicant meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.~~

~~—(d) An applicant meets all applicable requirements in the CON review standards for hospital beds.~~

Section 98. Requirements for approval ~~TO ACQUIRE~~ -- acquisition of a NICU service

Sec. 9. (1) An applicant proposing to acquire a NICU shall not be required to be in compliance with the needed NICU bed supply determined pursuant to Section 3 for the planning area in which the NICU subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in an increase in the number of hospital beds, or hospital beds designated for NICU services, at the licensed site to be acquired;

(b) the licensed site does not change as a result of the acquisition; and,

(c) the project does not involve the initiation, expansion or replacement of a covered clinical service, a covered capital expenditure for other than the proposed acquisition or a change in bed capacity at the applicant facility.

~~—(d) An applicant meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.~~

Section 109. Additional requirements for applications included in comparative reviews.

Sec. 109. (1) Any application subject to comparative review under Section 22229 of the Code or these standards shall be grouped and reviewed with other applications in accordance with the CON rules applicable to comparative reviews.

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards. If the Department determines that one or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as Potential Proposed Language for March 13, 2007 Commission Meeting

defined in Section 22225(1), ~~being Section 333.22225(1) of the Michigan Compiled Laws~~, and which have the highest number of points when the results of subsection (2) are totaled. If 2 or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) ~~of the Code, being Section 333.22225(1) of the Michigan Compiled Laws~~, which are proposed by an applicant that operates a NICU at the time an application is submitted to the Department. If 2 or more qualifying projects are determined to have an identical number of points and each operates a NICU at the time an application is submitted to the Department, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) ~~of the Code, being Section 333.22225(1) of the Michigan Compiled Laws~~, in the order in which the applications were received by the Department, based on the SUBMISSION date and time, AS DETERMINED BY THE DEPARTMENT ~~stamp placed on the application for CON form (form T-150-G-1.01 or any subsequent replacement form) by the Division of Health Facility Development (or the administrative unit of the Department responsible for administering the CON program) when an application is submitted.~~

(a) A qualifying project will have points awarded based on the geographic proximity to NICU services, both operating and CON approved but not yet operational, in accordance with the following schedule:

<u>Proximity</u>	<u>Points Awarded</u>
Less than 50 Miles (surface travel) to NICU service	0
Between 50-99 miles (surface travel) to NICU service	1
100+ Miles (surface travel) to NICU service	2

(b) A qualifying project will have points awarded based on the number of very low birth weight infants delivered at the applicant hospital or the number of very low birth weight infants admitted or refused admission due to the lack of an available bed to an applicant's NICU, and the number of very low birth weight infants delivered at another hospital subsequent to the transfer of an expectant mother from an applicant hospital to a hospital with a NICU. The total number of points to be awarded shall be the number of qualifying projects. The number of points to be awarded to each qualifying project shall be calculated as follows:

(i) Each qualifying project shall document, for the 2 most recent years for which verifiable data are available, the number of very low birth weight infants delivered at an applicant hospital, or admitted to an applicant's NICU, if an applicant operates a NICU, the number of very low birth weight infants delivered to expectant mothers transferred from an applicant's hospital to a hospital with a NICU, and the number of very low birth weight infants referred to an applicant's NICU who were refused admission due to the lack of an available NICU bed and were subsequently admitted to another NICU.

(ii) Total the number of very low birth weight births and admissions documented in subdivision (i) for all qualifying projects.

(iii) Calculate the fraction (rounded to 3 decimal points) of very low birth weight births and admissions that each qualifying project's volume represents of the total calculated in subdivision (ii).

(iv) For each qualifying project, multiply the applicable fraction determined in subdivision (iii) by the total possible number of points.

(v) Each qualifying project shall be awarded the applicable number of points calculated in subdivision (iv).

(c) An applicant shall have 1 point awarded if it can be demonstrated that on the date an application is submitted to the department, the licensed site at which NICU services/beds are proposed has on its active medical staff a physician(s) board certified, or eligible to be certified, in maternal/fetal medicine.

(d) A qualifying project will have points awarded based on the percentage of the hospital's indigent volume as set forth in the following table.

<u>Hospital Indigent Volume</u>	<u>Points Awarded</u>
0 - <6%	0.2
6 - <11%	0.4
11 - <16%	0.6
16 - <21%	0.8
21 - <26%	1.0
26 - <31%	1.2
31 - <36%	1.4
36 - <41%	1.6
41 - <46%	1.8
46% +	2.0

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the ~~Michigan Department of Social Services (MDSS) Medical Services Administration~~ **HOSPITAL AND HEALTH PLAN REIMBURSEMENT DIVISION** pursuant to ~~Chapter VIII SECTION 7~~ of the Medical ~~Assistance Program PROVIDER~~ manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(3) ~~No~~ **THE MINIMUM NUMBER OF** points will be awarded to an applicant under **THE INDIVIDUAL** ~~specific~~ subsections of **THIS** Section ~~40~~ **FOR CONFLICTING** ~~if~~ information presented in **THIS** section ~~40~~ **AND is inconsistent with** related information provided in other **SECTIONS** ~~portions~~ of the CON application.

SECTION 10. REQUIREMENTS FOR APPROVAL FOR ALL APPLICANTS

SEC. 10 AN APPLICANT SHALL PROVIDE VERIFICATION OF MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED.

Section 11. Project delivery requirements -- terms of approval for all applicants

Sec. 11. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

- (a) Compliance with these standards.
- (b) Compliance with applicable operating standards.
- (c) Compliance with the following applicable quality assurance standards:
 - (i) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
 - (A) not deny NICU services to any individual based on ability to pay or source of payment;
 - (B) provide NICU services to any individual based on clinical indications of need for the services;
 - (C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(ii) An applicant shall coordinate its services with other providers of obstetrical, perinatal, neonatal and pediatric care in its planning area, and other planning areas in the case of highly specialized services.

(iii) An applicant shall develop and maintain a follow-up program for NICU graduates and other infants with complex problems. An applicant shall also develop linkages to a range of pediatric care for high-risk infants to ensure comprehensive and early intervention services.

(iv) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain an outreach program that includes both case-

finding and social support which is integrated into perinatal care networks, as appropriate.

(v) If an applicant operates a NICU that admits infants that are born at a hospital other than the applicant hospital, an applicant shall develop and maintain a neonatal transport system.

(vi) An applicant shall coordinate and participate in professional education for perinatal and pediatric providers in the planning area.

(vii) An applicant shall develop and implement a system for discharge planning.

(viii) A board certified neonatologist shall serve as the director of neonatal services.

(ix) An applicant shall make provisions for on-site physician consultation services in at least the following ~~NEONATAL/PEDIATRIC sub~~-specialties: cardiology, ophthalmology, surgery and neurosurgery.

(x) An applicant shall develop and maintain plans for the provision of highly specialized ~~NEONATAL/PEDIATRIC~~ services, such as cardiac surgery, cardiovascular surgery, neurology, hematology, orthopedics, urology, otolaryngology and genetics.

(xi) An applicant shall develop and maintain plans for the provision of transferring infants discharged from its NICU to another hospital, as necessary for the care of an infant no longer requiring NICU services but unable to be discharged home.

(xii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each licensed site; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(xiii) The applicant shall provide the Department with a notice stating the date the initiation, expansion, replacement or relocation of the NICU service is placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(xiv) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(2) The agreements and assurances required by this section shall be in the form of a certification ~~authorized by the governing body of~~ AGREED TO BY the applicant or its authorized agent.

Section 12. Planning areas

Sec. 12. The planning areas for neonatal intensive care services/beds are the geographic ~~BOUNDARIES OF THE GROUP OF COUNTIES areas established for health system agencies pursuant to former Section 1511 by the Public Health Service Act. Counties assigned to each planning area are~~ as follows:

Planning Areas

Counties

1	Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne
2	Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee
3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van Buren
4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo, Oceana, Ottawa
5	Genesee, Lapeer, Shiawassee
6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland, Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola
7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, Montmorency, Otsego, Presque Isle, Roscommon, Wexford

8 Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron, Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon, Schoolcraft

Section 13. Department inventory of beds

| Sec. 13. The Department shall maintain, ~~and provide on request~~, a listing of the department inventory of beds for each planning area.

Section 14. Effect on prior CON review standards; comparative reviews

| Sec. 14. (1) These CON review standards supercede and replace the CON Review Standards for Neonatal Intensive Care and Special Newborn Nursery Services/Beds approved by the Commission on ~~April 19, 1995~~ MARCH 9, 2004 and effective on ~~June 9, 1995~~ JUNE 4, 2004.

(2) Projects reviewed under these standards shall be subject to comparative review except for:

(a) Replacement beds meeting the requirements of Section 22229(3) of the Code, being Section 333.22229(3) of the Michigan Compiled Laws;

| (b) The designation of beds for NICU services being relocated pursuant to Section ~~7-6~~ of these standards; or

| (c) Beds requested under Section ~~65~~(2).

CON REVIEW STANDARDS
FOR NEONATAL INTENSIVE CARE SERVICES/BEDS

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget